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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/189,543	11/10/98	CHEE	M A-66828-1/DJ

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FLEHR HOHBACH TEST ALBRITTON AND HERBERT
SUITE 3400
FOUR EMBARCADERO CENTER
SAN FRANCISCO CA 94111-4187

EXAMINER

MARSCHER, A	
ART UNIT	PAPER NUMBER

1631
DATE MAILED:

22
04/09/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trad marks

Office Action Summary

Application No.

09/189,543

Applicant(s)

Ch e et al.

Examiner

Ardin Marschel

Group Art Unit

1631



☒ Responsive to communication(s) filed on Jan 26, 2001

☐ This action is **FINAL**.

☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 35 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 3 month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claim

☒ Claim(s) 1-7 and 15-31 is/are pending in the application.
~~Of these, claim(s) 8-14 have been canceled.~~ ~~Claim(s) 8-14 have been withdrawn from consideration.~~

☐ Claim(s) _____ is/are allowed.

☒ Claim(s) 1-7 and 15-31 is/are rejected.

☐ Claim(s) _____ is/are objected to.

☐ Claims _____ are subject to restriction or election requirement.

Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some* ☒ None of the CERTIFIED copies of the priority documents have been
☐ received.

☐ received in Application No. (Series Code/Serial Number) _____

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☒ Notice of References Cited, PTO-892

☒ Information Disclosure Statement(s), PTO-1449, ~~PTO-1449~~ (4 sheets)

☐ Interview Summary, PTO-413

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

— SEE OFFICE ACTION ON THE FOLLOWING PAGES —

The request, filed 11/5/00, for a Continued Prosecution Application (CPA) under 37 CFR 1.53(d) based on parent Application No. 09/189,543 is acceptable and a CPA has been established. An action on the CPA follows.

Applicants' arguments, filed 1/26/01, have been fully considered but they are not deemed to be persuasive. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn. The following rejections and/or objections are either reiterated or newly applied. They constitute the complete set presently being applied to the instant application.

Claims 1-7 and 15-31 are rejected under 35 U.S.C. § 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

This rejection is reiterated from the previous office action, mailed 5/2/00, and as necessitated by amendment regarding newly added claims. Applicants arguments are replete with the acknowledgement that the invention is directed to the random distribution of microspheres on a patterned substrate or on a patterned surface of discrete sites. The presently pending claims only require that the substrate have discrete sites, over which the random microsphere distribution occurs, and lack the

limitation that these discrete sites are "patterned". This broadening of the practice of the sites on the substrate surface compared to the written support as pointed to by applicants for the microsphere distribution and its surface is NEW MATTER. It is recommended that applicants amend the claims in the phrases "discrete sites" or "individual sites" wherever they occur in the claims to be changed to "a patterned surface of discrete sites" to overcome this rejection. The random distribution of microspheres over such a patterned surface of discrete sites is acknowledged as having written support as filed, but not the broader phraseology without the "patterned" limitation.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. § 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

Claims 1, 3-5, 7, 15, 16, 18-22, and 25-31 are rejected under 35 U.S.C. § 102(e) as being clearly anticipated by Walt et al. (P/N 6,023,540).

In Figures 10B, in the SUMMARY OF THE INVENTION section in columns 3-4, and in the DETAILED DESCRIPTION... in columns 5-15 the disclosure of dye labeled microspheres attached to a fiber optical bundle with wells on its surface and its preparation is disclosed which anticipates the above listed instant claims. It is noted that the optical response of the microspheres is changed as a result of binding of entity "64", for example a fluorescent dye, to the microspheres as disclosed in the reference in column 11, lines 1-14, which anticipates the decoder binding ligand limitation of instant claim 3, for example.

Claims 1, 4, 5, 7, 18, 20, 30, and 31 are rejected under 35 U.S.C. § 102(b) and (e) as being clearly anticipated by Ekins et al. (P/N 5,516,635).

This rejection is maintained and reiterated from the previous office action, mailed 5/2/00, and as necessitated by amendment due to the newly added claims. It is firstly noted that none of the instant claims require that the subpopulations, such as first and second subpopulations, be different. It is also noted that these subpopulations are not mixed for distribution on the surface, nor that they are applied in a heterogeneous mixture onto the surface, and, nor that the surface is patterned in any way. It is noted that applicants acknowledge in arguments that the microspheres of Ekins et al. are attached, via antibodies, at particular locations which are present on the

surface. These particular locations are reasonably interpreted as being "discrete" as well as "individual" sites. These attachment sites are on the molecular scale and as such are discrete. Such discrete molecules on the surface inherently could even be visualized by electron microscopy if desired. When the microspheres of Ekins et al. are applied to the surface they are in a solution which permits their random movement to the surface and attachment wherever they encounter a binding entity which is recognized by one of said antibodies. The density of attachment exceeds 100 per 1 mm² as clearly noted in Ekins et al. in column 5, lines 17-20.

It is noted that the remaining claim limitations directed to nucleic acid or protein binding agents are disclosed in Ekins et al. in column 8, lines 14-62. Ekins et al. also cites several types of markers or labels in column 4, lines 10-17, some of which are fluorescent or enzyme markers. Solid supports, such as specifically described plastic walls of microtitre plates, are cited in column 7, lines 57-64, as also required in instant claims 18 and 20.

The following is a quotation of 35 U.S.C. § 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are

such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Subject matter developed by another person, which qualifies as prior art only under subsection (f) or (g) of section 102 of this title, shall not preclude patentability under this section where the subject matter and the claimed invention were, at the time the invention was made, owned by the same person or subject to an obligation of assignment to the same person.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. § 103, the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 C.F.R. § 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of potential 35 U.S.C. § 102(f) or (g) prior art under 35 U.S.C. § 103(a).

Claims 1-7, 18, 20, and 22-31 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Ekins et al. (P/N 5,516,635); taken in view of Matthews et al.

It is noted above that Ekins et al. describes the basic microsphere and array invention as instantly claimed but does not disclose the usage of a bound decoder ligand nor a non-labeled microsphere. Ekins et al., however, does describe the usage of enzyme markers or labels as noted above in column 4, lines 10-17. One interpretation of the instant claim limitations is that they are directed to markers which upon further development are labeled with a directly detectable label. It is noted in Matthews et al. as summarized below that enzymes are well known

as being attachable to biomolecules for subsequent development with a substrate which results in a label which is the actually detected entity. The enzyme is not directly detected as a label.

Matthews et al. is a review reference regarding various aspects of DNA probe usage but also contains references to commonality between immunoassays as well as noted on page 5, second column, last 3 lines. On page 6, Table 2, several labels types are listed including enzymes which apparently require further development with a substrate for detection. A particular cascade label which starts with an enzyme is described on pages 8-9, bridging paragraph. It is noted that these substrate usages may also be interpreted as decoder ligands which are bound to the immobilized microspheres after ligand detection via their attached antibody. This interpretation suggests and motivates a reasonable interpretation of the decoder ligand binding limitations of the instant claims.

Thus, it would have been obvious to someone of ordinary skill in the art at the time of the instant invention to practice the arrays and their preparation as given in Ekins et al. with enzyme labels which are later decoded via the binding of the appropriate enzyme substrate to result in the practice of the instant invention.

The non-statutory double patenting rejection, whether of the obviousness-type or non-obviousness-type, is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or

improper timewise extension of the "right to exclude" granted by a patent. *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); and *In re Goodman*, 29 USPQ2d 2010 (Fed. Cir. 1993).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(b) and (c) may be used to overcome an actual or provisional rejection based on a non-statutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.78(d).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-7 and 15-31 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-11 of copending application Serial No. 09/473,904. Although the conflicting claims are not identical, they are not patentably distinct from each other because the array compositions of each set of claims contain common embodiments of such arrays or the methods of making them which are deemed obviously required methodology therefor.

This is a *provisional* obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

It is acknowledged that the following applications have been considered: 09/473,904 and 09/187,289. However, the files for 09/748,706 and 09/606,369 were unavailable for consideration at this time due to being in a new application processing.

No claim is allowed.

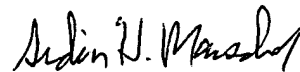
Papers related to this application may be submitted to Technical Center 1600 by facsimile transmission. Papers should be faxed to Technical Center 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notices published in the Official Gazette, 1096 OG 30 (November 15, 1988), 1156 OG 61 (November 16, 1993), and 1157 OG 94 (December 28, 1993) (See 37 CFR § 1.6(d)). The CM1 Fax Center number is either (703)308-4242 or (703)305-3014.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ardin Marschel, Ph.D., whose telephone number is (703)308-3894. The examiner can normally be reached on Monday-Friday from 8 A.M. to 4 P.M.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward, Ph.D., can be reached on (703)308-4028.

Any inquiry of a general nature or relating to the status of this application should be directed to Patent Analyst, Tina Plunkett, whose telephone number is (703)305-3524 or to the Technical Center receptionist whose telephone number is (703)308-0196.

April 6, 2001


ARDIN H. MARSCHEL
PRIMARY EXAMINER